K091359

3. 510(K) SUMMARY

SEP - 2 2009

1.	Applicant/Sponsor:	Gold Standard Orthopaedics, LLC. 1226 Rowan St. Louisville, KY 40203
2.	Contact Person:	David Baughman President David06@Baughmangroup.com Phone (502) 581-8770
3.	Proprietary Name:	GSO PCT Spinal System
4.	Common Name:	Posterior Spinal Implants
5.	Classification Names:	21 CFR 888.3050 – Spinal interlaminal fixation orthosis

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   - Mountaineer OCT Spinal System – Depuy Spine, Inc. (K080828)
   - Altius OCT System – Interpore Cross International (K033961)
   - OASYS System – Stryker Spine (K080143, K032394)
   - GS1 Spinal System – Gold Standard Orthopaedics, LLC (K070966)

7. Device Description:

   The GSO PCT Spinal System consists of rods, screws, hooks, and connecting components that can be locked rigidly into various configurations to build a spinal construct specific to the needs of each individual patient. The implants are attached to the spine posteriorly by means of screws and/or hooks joined with rods. Cross connector components are used to attach two rods in parallel. The GSO PCT Spinal System can be installed with any suitable instrumentation.

   The GSO PCT Spinal System components are manufactured from CP Titanium conforming to ASTM F67 and Ti-6Al-4V Titanium alloy conforming to ASTM F136. Devices are available in various diameters, lengths and sizes.

8. Intended Use:

   The GSO PCT Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. It is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The GSO PCT Spinal System should be removed after fusion.

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In all cases, instrumentation must be at least 1 cm from any major vessel.

9. Indications:

The GSO PCT Spinal System is intended to promote fusion of the cervical spine and cervico-thoracic junction (C1-T3), and is indicated for the following:

1. Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis
3. Spinal stenosis
4. Fracture or dislocation
5. Revision of previous cervical or cervico-throracic spine surgery
6. Tumors

The use of multi-axial pedicle screws is limited to placement in the upper thoracic spine (T1-T3) for the purpose of anchoring the construct. The multi-axial pedicle screws are not intended to be placed in the cervical spine.

10. Summary of Technologies/Substantial Equivalence:

The GSO PCT Spinal System has a similar indications and design and is manufactured from the same materials as the Mountaineer OCT Spinal System – Depuy Spine, Inc. (K080828), the Altius OCT System – Interpore Cross International (K033961), and the OASYS System – Stryker Spine (K080143, K032394)

11. Non-Clinical Testing:

Mechanical testing conducted according to ASTM F1717 demonstrates that the GSO PCT Spinal System has sufficient strength for its intended use.

12. Clinical Testing:

Clinical testing was not necessary to demonstrate the substantial equivalence of the GSO PCT Spinal System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Gold Standard Orthopaedics, LLC
% Mr. David Baughman
President
1226 Rowan Street
Louisville, Kentucky 40203

SEP - 2 2009

Re: K091359
Trade/Device Name: GSO PCT Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: August 23, 2009
Received: August 27, 2009

Dear Mr. Baughman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrer

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K091359

Device Name: GSO PCT Spinal System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen D. Burg for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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